4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5971]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations to Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0681. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recommendations To Reduce the Risk of Transfusion-Transmitted Infection in Whole Blood and Blood Components; Agency Guidance

OMB Control Number 0910-0681--Extension

Under § 630.3(h) (21 CFR 630.3(h)), a list is set forth of relevant transfusion-transmitted infections (RTTIs) (§ 630.3(h)(1)) and the conditions under which a transfusion-transmitted infection (TTI) would meet the definition of an RTTI (§ 630.3(h)(2)). The list of RTTIs under § 630.3(h)(1) includes, among other things, the following: *Trypanosoma cruzi* (Chagas), Creutzfeldt Jacob Disease (CJD)/variant Creutzfeldt Jacob Disease (vCJD), *plasmodium* species (malaria), and West Nile virus. The RTTIs FDA has identified thus far under § 630.3(h)(2) include Zika virus and babesiosis. In addition, FDA has determined Ebola virus to be a TTI identified under § 630.3(*l*). FDA has issued several guidance documents with recommendations regarding the RTTIs or TTIs including Chagas, babesiosis, Zika virus, West Nile virus, Ebola virus, malaria, CJD and vCJD, human immunodeficiency virus (HIV) and human T-lymphotropic virus, types I and II (HTLV).

The Chagas, babesiosis, Zika virus, West Nile virus, and HTLV guidance documents provide recommendations for consignee and physician notification relating to donors that tested reactive for these infections.

In addition, a blood establishment may receive information from a donor following collection that reveals the donor had a risk factor for an RTTI or TTI at the time of collection and should have been deferred for the risk factor. FDA has recommended, in the following guidance documents, that such a blood collection establishment notify the consignee regarding the distributed blood components that are potentially at-risk for an RTTI or TTI. In some cases, we recommend that if the blood was transfused, the consignee notify the transfusion recipient's physician of record regarding the potential risk. This recommendation is included in Ebola virus, malaria, CJD and vCJD, and HIV guidance documents. These guidance documents are available from our website at https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.

In the *Federal Register* of January 7, 2020 (85 FR 716), we published a 60-day notice requesting public comment on the proposed collection of information. For purposes of estimating burden under the PRA, we provided an estimate of one response and one burden hour annually. As we discussed in our 60-day notice, although such notifications are rare, we believe that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. In addition, we believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for a TTI. No comments were received in response to our 60-day notice, and we therefore retain this estimate. As other relevant transfusion-transmitted infections are determined under § 630.3, we may continue to issue guidance accordingly, and, if approved, intend the information collections to be included under this OMB control number.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. These guidance documents, as applicable, also refer to previously approved FDA collections of information. The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910-0338; the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910-0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910-0458.

Dated: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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